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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/537,027 | DEN HEUVEL ET AL. | |
| | Examiner | Art Unit | |
| | Jeffrey R. West | 2857 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *24 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *139-176* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *139-176* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 June 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

1. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

### *Continued Examination Under 37 CFR 1.114*

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 24, 2009, has been entered.

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 139-144, 147-152, 154-156, 159-165, and 168-174 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,916,291 to Givens et al.

With respect to claim 139, Givens discloses a system for performing a test of one or more tests on a prosthesis having one or more implantable components implanted in a recipient (column 10, lines 49-58 and column 13, lines 47-53) comprising: a clinician subsystem, comprising a clinician interface (column 8, lines 63-66, column 9, lines 12-24, and column 16, lines 20-29), configured to enable a clinician to provide one or more clinician input from said clinician interface to perform one or more of selecting and customizing the one or more tests for the recipient (column 9, lines 35-43, column 15, line 59 to column 16, line 29) and a recipient subsystem, comprising a recipient interface (column 8, lines 57-63, column 10, lines 17-24, and column 15, lines 29-58), configured to receive one or more recipient input, from said recipient interface (column 20, lines 15-17 and column 23, lines 41-44 and 54-60), and to perform the one or more tests received from and independent of the clinician subsystem on said prosthesis, in response to said user input to generate the result data (column 19, lines 48-60, column 20, lines 24-46 and column 23, lines 29-44 and 54-63) for communication to said clinician subsystem (column 13, lines 58-63), wherein said clinician subsystem is further configured to received said result data from said recipient subsystem (column 9, lines 47-51).

With respect to claim 140, Givens discloses further comprising: a device interface configured to communicatively couple said recipient subsystem and the prosthesis, and further configured to communicate the one or more tests from said recipient subsystem to the prosthesis (column 10, lines 49-58, column 19, lines 34-59 and Figure 11).

With respect to claim 141, Givens discloses further comprising: one or more computers configured to provide said clinician interface and said recipient interface (column 10, lines 17-32).

With respect to claim 142, Givens discloses wherein said computer configured to provide said clinician interface and said computer configured to provide said recipient interface are the same computer (column 24, lines 8-49).

With respect to claim 143, Givens discloses wherein said one or more computers configured to provide said clinician interface and recipient interface comprise a first computer configured to provide said clinician interface and a second computer configured to provide said recipient interface (column 10, lines 17-32).

With respect to claim 144, Givens discloses wherein said first and second computers are physically remote with respect to one another and are communicatively coupled to one another (column 8, line 57 to column 9, line 11).

With respect to claim 147, Givens discloses further comprising: a storage medium configured to store said selected or customized one or more tests (column 14, lines 57-59).

With respect to claim 148, Givens discloses further comprising: a storage medium configured to store said result data (column 9, lines 24-33).

With respect to claim 149, Givens discloses wherein said storage medium is a portable storage medium (column 8, lines 3-6).

With respect to claim 150, Givens discloses wherein the recipient subsystem is further configured to deliver the result data to the clinician subsystem, and further wherein the clinician subsystem is further configured to perform an assessment of the result data (column 18, lines 63-66).

With respect to claim 151, Givens discloses wherein the result data is configured to be delivered via the Internet (column 8, line 57 to column 9, line 11).

With respect to claim 152, Givens discloses wherein said device interface is an external port on said recipient subsystem (column 15, lines 45-47, column 19, lines 34-59, and Figure 11).

With respect to claim 154, Givens discloses wherein said clinician subsystem is configured to control said recipient subsystem as the one or more tests is being performed (column 4, lines 19-32 and column 15, lines 59-66).

With respect to claim 155, Givens discloses wherein said clinician subsystem is configured to commence the one or more tests being performed by the recipient interface (column 20, lines 17-23 and column 20, line 66 to column 21, line 8).

With respect to claim 156, Givens discloses a method for performing one or more tests on a prosthesis having one or more implantable components implanted in a recipient comprising (column 10, lines 49-58 and column 13, lines 47-53): selecting

one or more tests via a clinician subsystem, comprising a clinician interface (column 8, lines 63-66, column 9, lines 12-24, and column 16, lines 20-29), configured to allow a clinician to provide clinician input to the clinician interface to select the one or more tests for the recipient (column 15, line 59 to column 16, line 29), customizing said selected one or more tests using the clinician interface (column 9, lines 35-43, column 15, line 59 to column 16, line 29); delivering said customized one or more tests to a recipient subsystem (column 9, lines 35-43), comprising a recipient interface (column 8, lines 57-63, column 10, lines 17-24, and column 15, lines 29-58); performing said customized one or more tests on the prosthesis using the recipient subsystem and independent of the clinician subsystem (column 19, lines 48-60, column 20, lines 24-46 and column 23, lines 29-44 and 54-63), to generate the result data; and delivering the result data to the clinician subsystem (column 9, lines 47-51 and column 13, lines 58-63).

With respect to claim 159, Givens discloses wherein the recipient subsystem further comprises a storage medium, further comprising: storing said customized one or more tests for said delivering said customized one or more tests (column 14, lines 57-59).

With respect to claim 160, Givens discloses wherein the recipient subsystem further comprises a storage medium configured to store said result data (column 9, lines 24-33 and column 23, lines 23-27).

With respect to claim 161, Givens discloses wherein the storage medium is a portable storage medium (column 8, lines 3-6).

With respect to claim 162, Givens discloses wherein said delivering said customized one or more tests and the respective result data is delivered via the Internet (column 8, line 57 to column 9, line 11).

With respect to claim 163, Givens discloses wherein said performing said customized one or more tests further comprises: controlling the recipient subsystem as the one or more tests is being performed (column 4, lines 19-32 and column 15, lines 59-66).

With respect to claim 164, Givens discloses wherein said performing said customized one or more tests further comprises: commencing, but not controlling, the one or more tests being performed by the recipient interface (i.e. commence the test to be performed on the stand-alone recipient system) (column 20, lines 17-23 and column 20, line 66 to column 21, line 8).

With respect to claim 165, Givens discloses a computer readable medium comprising computer code instructions which, when executed by a computer system (column 8, lines 7-22), cause the computer system to perform a test method on a prosthesis having one or more implantable components implanted in a recipient (column 10, lines 49-58 and column 13, lines 47-53), the method comprising: selecting one or more tests via a clinician subsystem, comprising a clinician interface (column 8, lines 63-66, column 9, lines 12-24, and column 16, lines 20-29), configured to allow a clinician to provide clinician input to the clinician interface to select the one or more tests for the recipient (column 15, line 59 to column 16, line 29), customizing said selected one or more tests using the clinician interface

(column 9, lines 35-43, column 15, line 59 to column 16, line 29); delivering said customized one or more tests to a recipient subsystem (column 9, lines 35-43), comprising a recipient interface (column 8, lines 57-63, column 10, lines 17-24, and column 15, lines 29-58); performing said customized one or more tests on the prosthesis using the recipient subsystem and independent of the clinician subsystem (column 19, lines 48-60, column 20, lines 24-46 and column 23, lines 29-44 and 54-63), to generate the result data; and delivering the result data to the clinician subsystem (column 9, lines 47-51 and column 13, lines 58-63).

With respect to claim 168, Givens discloses wherein the recipient subsystem further comprises a storage medium, further comprising: storing said customized one or more tests for said delivering said customized one or more tests (column 14, lines 57-59).

With respect to claim 169, Givens discloses wherein the recipient subsystem further comprises a storage medium configured to store said result data (column 9, lines 24-33 and column 23, lines 23-27).

With respect to claim 170, Givens discloses wherein the storage medium is a portable storage medium (column 8, lines 3-6).

With respect to claim 171, Givens discloses wherein said delivering said customized one or more tests and the respective result data is delivered via the Internet (column 8, line 57 to column 9, line 11).

With respect to claim 172, Givens discloses wherein said performing said customized one or more tests further comprises: controlling the recipient subsystem

as the one or more tests is being performed (column 4, lines 19-32 and column 15, lines 59-66).

With respect to claim 173, Givens discloses wherein said performing said customized one or more tests further comprises: commencing, but not controlling, the one or more tests being performed by the recipient interface (i.e. commence the test to be performed on the stand-alone recipient system) (column 20, lines 17-23 and column 20, line 66 to column 21, line 8).

With respect to claim 174, Givens discloses a system for performing a test on a prosthesis having one or more implantable components implanted in a recipient (column 10, lines 49-58 and column 13, lines 47-53) comprising: means for selecting one or more tests via a clinician subsystem (column 8, lines 63-66, column 9, lines 12-24, and column 16, lines 20-29) configured to allow a clinician to provide clinician input to select the one or more tests for the recipient (column 15, line 59 to column 16, line 29); means for customizing said selected one or more tests (column 9, lines 35-43, column 15, line 59 to column 16, line 29); means for delivering said customized one or more tests to a recipient subsystem (column 9, lines 35-43); means for performing said customized one or more tests on the prosthesis, using the recipient subsystem and independent of the clinician subsystem (column 19, lines 48-60, column 20, lines 24-46 and column 23, lines 29-44 and 54-63), to generate the result data; and means for delivering the result data to the clinician subsystem (column 9, lines 47-51 and column 13, lines 58-63).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 145, 146, 153, 157, 158, 166, 167, 175, and 176 are rejected under 35 U.S.C. 103(a) as being unpatentable over Givens in view of U.S. Patent No. 5,626,629 to Faltys et al.

As noted above, the invention of Givens teaches many of the features of the claimed invention, and while the invention of Givens does teach testing, using customized tests, a prosthesis which generates test results, Givens is not explicit in storing such tests/results in the prosthesis. Further, while Givens does teach coupling the prosthesis to a recipient subsystem, Givens is not explicit in specifying that the coupling is via a cable.

Faltys discloses a system for performing one or more tests (column 7, lines 10-13 and 22-26, column 8, lines 44-55, column 9, lines 6-16, and column 10, lines 10-12) on a prosthesis having one or more implantable components implanted in a recipient (column 5, lines 19-21) comprising: a clinician subsystem, comprising a clinician interface (column 5, lines 35-50), configured to enable a clinician to provide one or more clinician input from said clinician interface to perform one or more of selecting and customizing the one or more tests for the recipient (column 6, lines 51-

55, column 7, lines 41-65, column 10, lines 26-53, and column 15, lines 34-55, and column 22, lines 51-53); and a recipient subsystem, comprising a recipient interface (column 5, lines 51-66), configured to receive one or more recipient input, from said recipient interface (column 4, lines 22-25), and to generate the result data (column 6, lines 51-55, column 14, line 53 to column 15, line 6), wherein said clinician subsystem is further configured to received said result data from said recipient subsystem (column 8, lines 10-43) wherein the prosthesis is configured to store said selected or customized one or more tests (column 6, lines 51-55 and column 9, lines 40-61), store said result data (column 9, lines 57-61), and is coupled to said recipient subsystem using a cable (column 5, line 51 to column 6, line 17 and Figure 1).

It would have been obvious to one having ordinary skill in the art to modify the invention of Givens to explicitly store the tests/results in the prosthesis, as taught by Faltys, because, as suggested by Faltys, the combination would have improved the system of Givens by storing important information in the prosthesis itself so that the data will be readily available for future use and/or to provide to a clinician when the network connection fails or during routine in-office clinician visits (column 2, lines 51-65, column 6, lines 51-55 and column 9, lines 40-61).

It would have been obvious to one having ordinary skill in the art to modify the invention of Givens to explicitly specify that the coupling is via a cable, as taught by Faltys, because one having ordinary skill in the art would recognize a cable as a conventional means for connecting a prosthesis to an interface and, as suggested by Faltys, the combination would have provides a suitable, accurate, and secure

means for connecting the prosthesis and interface for communication in Givens (column 5, line 51 to column 6, line 17 and Figure 1).

7. Claims 139-176 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,626,629 to Faltys et al. in view of U.S. Patent No. 5,909,497 to Alexandrescu.

With respect to claim 139, Faltys discloses a system for performing one or more tests (column 7, lines 10-13 and 22-26, column 8, lines 44-55, column 9, lines 6-16, and column 10, lines 10-12) on a prosthesis having one or more implantable components implanted in a recipient (column 5, lines 19-21) comprising: a clinician subsystem, comprising a clinician interface (column 5, lines 35-50), configured to enable a clinician to provide one or more clinician input from said clinician interface to perform one or more of selecting and customizing the one or more tests for the recipient (column 6, lines 51-55, column 7, lines 41-65, column 10, lines 26-53, and column 15, lines 34-55, and column 22, lines 51-53); and a recipient subsystem, comprising a recipient interface (column 5, lines 51-66), configured to receive one or more recipient input, from said recipient interface (column 4, lines 22-25), and to generate the result data (column 6, lines 51-55, column 14, line 53 to column 15, line 6), wherein said clinician subsystem is further configured to received said result data from said recipient subsystem (column 8, lines 10-43).

With respect to claim 140, Faltys discloses a device interface configured to communicatively couple said recipient subsystem and the prosthesis, and further

configured to communicate the one ore more tests from said recipient subsystem to the prosthesis (column 5, line 51 to column 6, line 17 and Figure 1).

With respect to claim 141, Faltys discloses one or more computers configured to provide said clinician interface and said recipient interface (column 5, lines 21-30).

With respect to claim 142, Faltys discloses that said computer configured to provide said clinician interface and said computer configured to provide said recipient interface are the same computer (column 5, lines 21-30 and column 22, line 61 to column 23, line 7).

With respect to claim 145, Faltys discloses that the prosthesis is configured to store said selected or customized one or more tests (column 6, lines 51-55 and column 9, lines 40-61).

With respect to claim 146, Faltys discloses that the prosthesis is configured to store said result data (column 9, lines 57-61).

With respect to claim 147, Faltys inherently discloses a storage medium configured to store said selected or customized one or more tests (column 6, lines 43-55).

With respect to claim 148, Faltys inherently discloses a storage medium configured to store said result data (column 6, lines 60-63 and column 7, lines 41-65).

With respect to claim 149, Faltys discloses that said storage medium is a portable storage medium (column 22, lines 35-44).

With respect to claim 150, Faltys discloses that the recipient subsystem is further configured to deliver the result data to the clinician subsystem, and further wherein the clinician subsystem is further configured to perform an assessment of the result data (column 8, lines 2-43).

With respect to claim 152, Faltys discloses that said device interface is an external port on said recipient subsystem (column 5, line 51 to column 6, line 17, Figure 1, and column 22, line 61 to column 23, line 7).

With respect to claim 153, Faltys discloses a cable coupled between said recipient subsystem and said prosthesis (column 5, line 51 to column 6, line 17 and Figure 1)

With respect to claim 154, Faltys discloses that said clinician subsystem is configured to control said recipient subsystem as the one or more tests is being performed (column 17, lines 35-57).

With respect to claim 155, Faltys discloses that said clinician subsystem is configured to commence the one or more tests being performed by the recipient interface (column 15, lines 19-28, column 15, lines 37-48, column 16, lines 36-38).

With respect to claim 156, Faltys discloses a method for performing one or more tests (column 7, lines 10-13 and 22-26, column 8, lines 44-55, column 9, lines 6-16, and column 10, lines 10-12) on a prosthesis having one or more implantable components implanted in a recipient (column 5, lines 19-21) comprising: selecting one or more tests via a clinician subsystem, comprising a clinician interface (column 5, lines 35-50), configured to allow a clinician to provide clinician input to the clinician

interface to select the one or more tests for the recipient (column 7, lines 41-65 and column 15, lines 34-55); customizing said selected one or more tests using the clinician interface (column 6, lines 51-55, column 7, lines 41-65, column 10, lines 26-53, and column 15, lines 34-55, and column 22, lines 51-53); delivering said customized one or more tests to a recipient subsystem (column 6, lines 51-55 and column 9, lines 40-61), comprising a recipient interface (column 5, lines 51-66); performing said customized one or more tests on the prosthesis to generate the result data (column 6, lines 51-55, column 14, line 53 to column 15, line 6); and delivering the result data to the clinician subsystem (column 8, lines 2-43).

With respect to claim 157, Faltys discloses that the prosthesis is configured to store said customized one or more tests (column 6, lines 51-55 and column 9, lines 40-61).

With respect to claim 158, Faltys discloses that the prosthesis is configured to store said result data (column 9, lines 57-61).

With respect to claim 159, Faltys inherently discloses that the recipient subsystem further comprises a storage medium further comprising storing said customized one or more tests for said delivering said customized one or more tests (column 6, lines 51-55 and column 9, lines 40-61).

With respect to claim 160, Faltys inherently discloses that the recipient subsystem further comprises a storage medium configured to store said result data (column 9, lines 57-61).

With respect to claim 161, Faltys discloses that the storage medium is a portable storage medium (i.e. as part of a portable device) (column 6, lines 51-55 and column 9, lines 40-61).

With respect to claim 163, Faltys discloses that performing said customized one or more tests further comprises: controlling the recipient subsystem as the one or more tests is being performed (column 17, lines 35-57).

With respect to claim 164, Faltys discloses that performing said customized one or more tests further comprises: commencing, but not controlling, the one or more tests being performed by the recipient interface (i.e. in the sweep test, for example, the test is commenced after which time the test proceeds automatically to repeat current application without any subsequent control as long as the tones are in sequence) (column 16, lines 36-49).

With respect to claim 165, Faltys discloses a computer readable medium comprising computer code instructions which, when executed by a computer system, cause the computer system to (column 5, lines 19-25) perform a test method on a prosthesis having one or more implantable components implanted in a recipient (column 5, lines 19-21), the method comprising: selecting one or more tests (column 7, lines 10-13 and 22-26, column 8, lines 44-55, column 9, lines 6-16, and column 10, lines 10-12) via a clinician subsystem, comprising a clinician interface (column 5, lines 35-50), configured to allow a clinician to provide clinician input to the clinician interface to select the one or more tests for the recipient (column 7, lines 41-65 and column 15, lines 34-55); customizing said selected one or more tests

using the clinician interface (column 6, lines 51-55, column 7, lines 41-65, column 10, lines 26-53, and column 15, lines 34-55, and column 22, lines 51-53); delivering said customized one or more tests to a recipient subsystem (column 6, lines 51-55 and column 9, lines 40-61), comprising a recipient interface (column 5, lines 51-66); performing said customized one or more tests on the prosthesis using the recipient subsystem to generate the result data (column 6, lines 51-55, column 14, line 53 to column 15, line 6); and delivering the result data to the clinician subsystem (column 8, lines 2-43).

With respect to claim 166, Faltys discloses that the prosthesis is configured to store said customized one or more tests (column 6, lines 51-55 and column 9, lines 40-61).

With respect to claim 167, Faltys discloses that the prosthesis is configured to store said result data (column 9, lines 57-61).

With respect to claim 168, Faltys inherently discloses that the recipient subsystem further comprises a storage medium further comprising storing said customized one or more tests for said delivering and customized one or more tests (column 6, lines 51-55 and column 9, lines 40-61).

With respect to claim 169, Faltys inherently discloses that the recipient subsystem further comprises a storage medium configured to store said result data (column 9, lines 57-61).

With respect to claim 170, Faltys discloses that the storage medium is a portable storage medium (i.e. as part of a portable device) (column 6, lines 51-55 and column 9, lines 40-61).

With respect to claim 172, Faltys discloses that performing said customized one or more tests further comprises: controlling the recipient subsystem as the one or more tests is being performed (column 17, lines 35-57).

With respect to claim 173, Faltys discloses that performing said customized one or more tests further comprises: commencing, but not controlling, the one or more tests being performed by the recipient interface (i.e. in the sweep test, for example, the test is commenced after which time the test proceeds automatically to repeat current application without any subsequent control as long as the tones are in sequence) (column 16, lines 36-49).

With respect to claim 174, Faltys discloses a system for performing a test of a prosthesis having one or more implantable components implanted in a recipient (column 5, lines 19-21) comprising: means for selecting one or more tests (column 7, lines 10-13 and 22-26, column 8, lines 44-55, column 9, lines 6-16, and column 10, lines 10-12) via a clinician subsystem (column 5, lines 35-50) configured to allow a clinician to provide clinician input to select the one or more tests for the recipient (column 7, lines 41-65 and column 15, lines 34-55); means for customizing said selected one or more tests (column 6, lines 51-55, column 7, lines 41-65, column 10, lines 26-53, and column 15, lines 34-55, and column 22, lines 51-53); means for delivering said customized one or more tests (column 6, lines 51-55 and column 9,

lines 40-61) to a recipient subsystem (column 5, lines 51-66); means for performing said customized one or more tests on the prosthesis, using the recipient subsystem to generate the result data (column 6, lines 51-55, column 14, line 53 to column 15, line 6); and means for delivering the result data to the clinician subsystem (column 8, lines 2-43).

With respect to claim 175, Faltys discloses that the prosthesis is configured to store said customized one or more tests (column 6, lines 51-55 and column 9, lines 40-61).

With respect to claim 176, Faltys discloses that the prosthesis is configured to store said result data (column 9, lines 57-61).

As noted above, the invention of Faltys teaches many of the features of the claimed invention and while the invention of Faltys does teach a computer that process software instructions and output signals to perform testing of a hearing prosthesis through a recipient interface as well as allowing visualization of results by a clinician through a clinician interface, Faltys does not explicitly indicate that the interfaces are provided by separate remote computers connected by the Internet to allow independent testing to be performed by the recipient interface.

Alexandrescu teaches a programmable hearing aid instrument and programming method thereof including a recipient interface (column 4, lines 4-19) provided by a computer located remote from a clinician interface (column 8, lines 19-33) wherein the recipient interface is operable to obtain software instructions from the hearing prosthesis (column 5, lines 37-49), perform independent testing using the recipient

interface (column 8, lines 19-33) and deliver data specific to the hearing prosthesis (i.e. results) electronically to the clinician/specialist interface (column 5, lines 17-20) using the Internet (column 7, line 66 to column 8, line 4).

It would have been obvious to one having ordinary skill in the art to modify the invention of Faltys to explicitly indicate that the interfaces are provided by separate remote computers connected by the Internet to allow independent testing to be performed by the recipient interface, as taught by Alexandrescu, because, as suggested by Alexandrescu, the combination would have improved the recipient's programming of the device by providing specific programming for the environment in which the recipient is intending to use the device (column 8, lines 19-33) while allowing an experienced specialist to obtain response data from the environment to aid in tailoring the response parameters for the particular environment (column 1, lines 11-18, column 5, lines 17-20, and column 8, lines 5-18).

### *Response to Arguments*

8. Applicant's arguments filed March 24, 2009, have been fully considered but they are not persuasive.

Applicant argues:

> 7. Givens is directed to performing diagnostic hearing tests which use a computer network to allow interactions between a test administration site and one or a plurality of remote patient sites. (See, Givens, Abstract; col. 8, ln. 57.) In Givens, "the test is relayed from the test administration site 10 to a desired patient or local site 20 through the use of a computer network 15." (See, Givens, col. 8, ln. 67 - col. 9, ln. 3.) According to Givens, "in operation, the test is **administered by a clinician or audiologist at the test administration site 10**, remote from the patient site 20, in a manner which can allow

> **interaction...between the user and the clinician during** at least a portion of the administration of the test." (See, Givens, col. 9, 11. 13-17; emphasis added.) Furthermore, Givens states that "the system can be configured to allow the **clinician at the test administration site 10 to control the test** sequence and auditory hearing assessment tones from the remote administration site. Thus, the hearing test can be performed such that the hearing tones are generated and output locally at the patient site 20 in response to **commands selecting the desired tone / level which are transmitted from the expert or test administration site** to the local site via the computer network." (See, Givens, col. 9, 11. 35-43; emphasis added.) It is clear that the device and system described in Givens is controlled by or operated by an expert / clinician from the "test administration site".

The Examiner first asserts that while Givens may disclose an embodiment where the test is controlled by a clinician, such an embodiment does not preclude the disclosure of a different embodiment where the test is controlled by a recipient subsystem independent of a clinician subsystem.

Secondly, the Examiner asserts that, while the claims (i.e. claim 139) do require "a recipient subsystem...to perform the one or more tests...independent of the clinician subsystem", this does not mean that there is no interaction between the recipient subsystem and the clinician subsystem as the claims further require “a recipient subsystem...to perform the one or more tests received from...the clinician subsystem" and "to generate the result data for communication to said clinician subsystem".

The Examiner also asserts that Givens does disclose such an embodiment where the test is controlled by a recipient subsystem independent of a clinician subsystem. Specifically, Givens discloses a recipient subsystem, comprising a recipient interface:

As noted above, the present invention provides systems, methods and associated devices for performing interactive diagnostic hearing tests which use a computer network to allow interaction between a test administration site and one or a plurality of remote ("local") patient sites. The term "patient" refers to the individual(s) being tested and can include the user, subject, or client at the local site. (column 8, lines 57-63)

In certain embodiments, as illustrated in FIG. 2A the local system 20s is configured as a portable relatively inexpensive self-contained device 50, which can operate independent of a personal computer and is configured to interface with a computer network 15. In other embodiments, as shown in FIG. 2B, the local system 20s can include a device 50' which is configured to operate with a personal computer 75 or other general purpose data processing system. (column 10, lines 17-24)

Turning to FIG. 6, in other embodiments, the device 50' is configured to connect with a local computer such as a personal computer. The local computer 75 can be any suitable type whether a palm, laptop or desktop computer and the like. Alternatively, the local computer 75 may be pervasive computing device such as a smartphone or a PDA. Thus, in this embodiment, the device 50' includes the tone generator 55 and tone output port 60p. Optionally, in some embodiments, the device 50' may also include the microphone 80 and the audio analyzer 82. The device 50' may be provided as an internal for incorporation into the local computer 75 or as an external device. For example, the device 50' may be provided as a plug-in module, such as a "Springboard" for inclusion in a Visor PDA from Handspring. Alternatively, the device 50' may be a PCMCIA card which may be readily plugged into a laptop or other such general-purpose computer. Furthermore, the device 50' may be a separate unit which connects to, for example, the serial port of a general-purpose computer.

As shown in FIG. 5, the processor 70p, web pages 70c, TCP stack 70t and Enterhnet NIC 70n can be provided by the local computer 75. In this embodiment, the display screen and/or keyboard of the local computer 75 may be used as the input device 72 (or may be used along with an input device in the device 50'). Similarly, the video link described above may be provided by the local computer 75. The operational software needed to supplement the local operating system may be provided as a packaged product which is downloadable onto the local computer or may be provided at a URL location to be electronically downloadable therefrom. (column 15, lines 29-58)

configured to receive one or more recipient input, from said recipient interface:

Thus, the local device can be configured to allow a local operator to power up and depress a "ready button" when the probe assembly is in position. (column 20, lines 15-17)

The client 1600 displays the status information for the operator and determines, for example, by receiving input from the operator, if any parameters are to be changed (block 1720).

...

When no parameters are to be changed (block 1720), the client 1600 instructs the web server 1610 to initiate the stimulation (block 1735). The web server 1610 initiates the stimulation by the audiometer 1620, either directly or through the interface 1615, and collects data on the patient response (block 1740), either directly or through the interface 1615. (column 23, lines 41-44 and 54-60)

and to perform the one or more tests received from and independent of the clinician subsystem on said prosthesis, in response to said user input to generate the result data:

The local device 450, as for devices 50, 50', can be configured as a stand alone device (as shown), preferably with signal and data processing capability, and remote communication link 450c (whether via one or more of wireless, tower or satellite transmission, cable, telephone, fiber optic, or other communication link) so as to be able to transfer or upload data to (and preferably from as well) the remote location. In certain embodiments, the local device 450 is portable and may be implemented as a pervasive computing device that is configured to generate the desired test signals and to receive the response signals and relay the information to the remote site via the communication link 450c. (column 19, lines 48-60)

Referring to FIG. 11, in operation, in certain embodiments, the local device 450 is configured to generate stimulation signals corresponding to the testing protocol associated with the desired test (such as middle ear compliance or distortion product type evaluations). The stimulation signals 480 are transmitted from an output source located in the ear probe assembly 475, such as one or more speakers 482 having suitable operating characteristics in the desired frequency range (such as model ER-2 speakers from Etymotic Research Corporation, believed to have a relatively flat response from about 200 Hz-10 kHz). The probe assembly 475 can also include one or more sensors 483 such as transducers and/or one or more miniaturized low noise microphones oriented and configured to sense signals evoked in the ear of the subject. The sensor

> 483 detects the evoked response signal and relays the signal (typically as a digital signal converted by an A/D converter, as well known to those of skill in the art) to the local device 450. The local device 450 can directly relay the detected signals in the form in which they are received. Alternatively, the local device 450 (or associated computer or signal processor) can process the received signals into a desired format before transmitting to the remote site. (column 20, lines 24-46)
>
> FIG. 17 illustrates operations according to embodiments of the present invention. The operations illustrated in FIG. 17 may be carried out by the system of FIG. 16. As seen in FIG. 17, the client 1600 pings the web server 1610 (block 1700). If a response to the ping is not received (block 1705), operations may terminate or the ping of a same IP address or a different IP address may be performed until a response is received. If a response to the ping is received (block 1705), the client 1600 initiates a status request to the web server 1610 (block 1710). The web server 1610 collects the requested status information, for example, by requesting information from the audiometer 1620, and returns the status information to the client 1600 (block 1715). The client 1600 displays the status information for the operator and determines, for example, by receiving input from the operator, if any parameters are to be changed (block 1720).
> ...
> When no parameters are to be changed (block 1720), the client 1600 instructs the web server 1610 to initiate the stimulation (block 1735). The web server 1610 initiates the stimulation by the audiometer 1620, either directly or through the interface 1615, and collects data on the patient response (block 1740), either directly or through the interface 1615. The response data is provided to the client 1600 (block 1745) for display to the operator. If more tests are to be performed (block 1750), operations may continue from block 1720. (column 23, lines 29-44 and 54-63)

As can be seen by the cited sections above, Givens discloses embodiments where the recipient subsystem is a "pervasive computing device that is configured to generate the desired test signals and to receive the response signals", "is configured to generate stimulation signals corresponding to the testing protocol associated with the desired test", is coupled to a probe that includes "one or more sensors 483 such as transducers and/or one or more miniaturized low noise microphones oriented and configured to sense signals evoked in the ear of the subject", and "can process the

received signals into a desired format before transmitting to the remote site", all indicating that the recipient subsystem performs the testing independent of the clinician subsystem.

Givens further discloses an embodiment where the remote site (i.e. client 1600) communicates with the local site (i.e. web server 1610) and "client 1600 instructs the web server 1610 to initiate the stimulation", "server 1610 initiates the stimulation by the audiometer 1620, either directly or through the interface 1615, and collects data on the patient response" and "response data is provided to the client 1600 (block 1745) for display to the operator". Therefore, while the remote site does instruct the local site to initiate the testing, the test generation and receiving test responses are performed by the local site, independent of the remote site.

Applicant argues:

> 8. Regarding the recipient's response, Givens makes clear that "the system is also configured to **accept the patient's input or response during the test and transmit** the associated data back **to the administration site where it can be considered and evaluated**. The system can also allow the **test administrator** (typically an audiologist) to adjust the test sequence or tone based on the patient's indicated response **during** the testing protocol." (See, Givens, col. 9, 11. 47-52; emphasis added.) Again, Givens contemplates what may be characterized as a real-time testing situation in which the recipient's (patient's) response is transmitted to the audiologist during the test, and where the test itself is being controlled by the audiologist. As one having skill in the art will appreciate, the testing device and method in Givens is similar to a conventional in-clinic testing situation except that the signals travel over a network to a recipient who is remote.

The Examiner again asserts that, while the claims (i.e. claim 139) do require "a recipient subsystem...to perform the one or more tests...independent of the clinician

subsystem", this does not mean that there is no interaction between the recipient subsystem and the clinician subsystem as the claims further require “a recipient subsystem...to perform the one or more tests received from...the clinician subsystem" and "to generate the result data for communication to said clinician subsystem". Therefore, while Applicant argues that Givens discloses transmission of data back to the administrator, the claims themselves require the recipient subsystem "to generate the result data for communication to said clinician subsystem".

Applicant argues:

9. Applicants' independent claim 139 recites, in part, "a recipient subsystem, comprising a recipient interface, configured to receive one or more recipient input, from said recipient interface, and to **perform the one or more tests received from and independent of the clinician subsystem** on said prosthesis, in response to said user input, to generate the result data for communication to said clinician subsystem." (See, Applicants' independent claim 139, above; emphasis added.) Applicants assert that the testing device and method of Givens fails to anticipate or render obvious at least these elements of Applicants' claim 139. Similarly, Applicants' independent claims 156 and 165 recite, in part, "**performing** said customized one or more tests on the prosthesis, **using the recipient subsystem and independent of the clinician subsystem**, to generate the result data." (See, Applicants' independent claims 156 and 165, above; emphasis added.) Finally, Applicants' independent claim 174 recites, in part, "**means for performing** said customized one or more tests on the prosthesis, **using the recipient subsystem and independent of the clinician subsystem**, to generate the result data." (See, Applicants' independent claim 174, above; emphasis added.)

10. As noted above, Givens describes a system in which the test is being performed by the clinician's computer **via** the recipient's computer. Temporally speaking, the Givens testing system requires that the clinician's computer and the recipient's computer cooperate or interact during the entire test. In other words, in Givens, the clinician's computer transmits the test, which causes the test to be performed on the recipient's hearing prosthesis by the clinician's computer, followed by a response sent back to the clinician's computer.

> Therefore, Givens fails to describe performing the test "independent of the clinician subsystem" or "using the recipient subsystem and independent of the clinician subsystem" as claimed by Applicants.

Similar to the arguments provided above, while Applicant argues that Givens does not teach performing the one or more tests independent of the clinician subsystem because "in Givens, the clinician's computer transmits the test, which causes the test to be performed on the recipient's hearing prosthesis by the clinician's computer, followed by a response sent back to the clinician's computer", the Examiner asserts that the claims themselves require a clinician subsystem that transmits the test to the recipient subsystem and receives a response sent back from the recipient subsystem to the clinician subsystem, specifically: "a recipient subsystem...to perform the one or more tests received from...the clinician subsystem" and "to generate the result data for communication to said clinician subsystem".

The Examiner also maintains that, as noted above, Givens discloses embodiments where the recipient subsystem is a "pervasive computing device that is configured to generate the desired test signals and to receive the response signals", "is configured to generate stimulation signals corresponding to the testing protocol associated with the desired test", is coupled to a probe that includes "one or more sensors 483 such as transducers and/or one or more miniaturized low noise microphones oriented and configured to sense signals evoked in the ear of the subject", and "can process the received signals into a desired format before

transmitting to the remote site", all indicating that the recipient subsystem performs the testing independent of the clinician subsystem.

Furthermore, Applicant's argument is not considered to be persuasive as Applicant's claimed invention also requires controllin initiation of the test on the recipient subsystem by the clinician subsystem, for example, in claim 155 which depends from 139:

> 155. (Previously Presented) The system of claim 139, wherein said clinician subsystem is configured to commence the one or more tests being performed by the recipient interface.

Applicant argues:

> 11. Furthermore, the Examiner asserts that Givens describes "to perform the one or more tests received from and independent of the clinician subsystem on said prosthesis, in response to said user input to generate the result data ([Givens,] column 19, lines 48-60, column 20, lines 24-46 and column 23, lines 29-44 and 54-63." (See, Office Action, pg. 3.) Applicants assert that the Examiner is misunderstanding or misapplying Givens in at least the following ways.
>
> 12. First, the "stand alone device" described in column 19, line 49 of givens refers to a stand alone device which has its own "remote communication link". This is made clear by the sentence subsequent to the portion cited by the Examiner, which states, "**Alternatively**, the local device 450 can be configured to be operatively engageable with a local computer or pervasive communications device during the test, which in turn, may **provide the modem or communication link to the network 15 and to the remote [clinician's] site**." (See, Givens, col. 19, 11. 60-65; emphasis added.) Clearly, the portion relied upon by the Examiner and the next sentence cited above refer to embodiments of the Givens system which either has a communications link built-in to the recipient's system or a separate (not stand-alone) hardware which provides that communications link to the clinician's computer.

The Examiner asserts that column 19, lines 48-60 of Givens discloses:

> The local device 450, as for devices 50, 50', can be configured as a stand alone device (as shown), preferably with signal and data processing capability,

> and remote communication link 450c (whether via one or more of wireless, tower or satellite transmission, cable, telephone, fiber optic, or other communication link) so as to be able to transfer or upload data to (and preferably from as well) the remote location. In certain embodiments, the local device 450 is portable and may be implemented as a pervasive computing device that is configured to generate the desired test signals and to receive the response signals and relay the information to the remote site via the communication link 450c. (column 19, lines 48-60)

As discussed above, this section is relied upon for teaching that the "local device 450 is portable and may be implemented as a pervasive computing device that is configured to generate the desired test signals and to receive the response signals and relay the information to the remote site via the communication link 450c".

The Examiner also asserts that Applicant's indication that Givens discloses a "communications link to the clinician's computer" does not indicate that the one or more tests are not performed independent clinician subsystem since, as discussed above, the claims themselves require such a communication link between the recipient and clinician subsystems.

Applicant argues:

> 13. Second, the Examiner appears to rely on a portion of Givens as describing Applicants' the recipient-computer performing tests "received from and independent of the clinician subsystem." (See, Office Action, pg. 3.) In fact, Givens states, "the local device 450 is configured to generate **stimulation signals** corresponding to the testing protocol associated with the desired test." (See, Givens, col. 20, 11. 25-28; emphasis added.) As one having ordinary skill in the art will appreciate, this portion of Givens is describing what the recipient computer does with the test received from, and still controlled by, the clinician's system. In conjunction with FIG. 11 of Givens, this portion of Givens is describing the generation of the actual **stimulation signals 480** which are provided to the patient. This is apparent in Givens, which states, "the stimulation signals 480 are transmitted from an output source located in the ear probe assembly 475, such

as one or more speakers 482 having suitable operating characteristics in the desired frequency range." (See, Givens, col. 20, 11. 28-32; emphasis added.) Clearly, as can be seen in FIG. 11 of Givens, the stimulation signals 480 are those which are presented to the patient. Therefore, even this portion of Givens relied upon by the Examiner describes a test that is still controlled by, and therefore not independent from, the clinician's computer.

The Examiner asserts that column 20, lines 24-46 of Givens discloses

Referring to FIG. 11, in operation, in certain embodiments, the local device 450 is configured to generate stimulation signals corresponding to the testing protocol associated with the desired test (such as middle ear compliance or distortion product type evaluations). The stimulation signals 480 are transmitted from an output source located in the ear probe assembly 475, such as one or more speakers 482 having suitable operating characteristics in the desired frequency range (such as model ER-2 speakers from Etymotic Research Corporation, believed to have a relatively flat response from about 200 Hz-10 kHz). The probe assembly 475 can also include one or more sensors 483 such as transducers and/or one or more miniaturized low noise microphones oriented and configured to sense signals evoked in the ear of the subject. The sensor 483 detects the evoked response signal and relays the signal (typically as a digital signal converted by an A/D converter, as well known to those of skill in the art) to the local device 450. The local device 450 can directly relay the detected signals in the form in which they are received. Alternatively, the local device 450 (or associated computer or signal processor) can process the received signals into a desired format before transmitting to the remote site. (column 20, lines 24-46)

The Examiner disagrees with Applicant's assertion that by having the recipient subsystem receive test information from the clinician subsystem that the clinician subsystem is controlling the test. Instead, this section indicates that while the clinician subsystem does generate tests for the recipient subsystem to perform, the stimulation signal generation, response reception, and response processing is all carried out by the recipient subsystem. As such, the Examiner asserts that this section of Givens clearly discloses the claimed “a recipient subsystem, comprising a

recipient interface, configured…to perform the one or more tests received from and independent of the clinician subsystem on said prosthesis"

Furthermore, Applicant's argument is not considered to be persuasive as Applicant's claimed invention also requires control of the recipient subsystem by the clinician subsystem during testing, for example, in claim 154 which depends from 139:

> 154. (Previously Presented) The system of claim 139, wherein said clinician subsystem is configured to control said recipient subsystem as the one or more tests is being performed.

Applicant argues:

> 14. Finally, the Examiner appears to believe that the server / client configuration described in Givens at column 23, lines 29-44 and 54-63 and illustrated in FIG. 17 is describing a system in which a "client" interacts with a server to perform a test, where the "client" is apparently believed to represent the patient. (See, Office Action, pg. 3.) In fact, Applicants note that Givens, in describing its FIG. 16, actually refers to a "client" in a client / server context as will be known to persons having ordinary skill in the computer arts. Furthermore, this section of Givens relied upon by the Examiner is describing a system in which a third computer, apart from the clinician's computer and the patient's computer, can be used to "change parameters" on the patient's hearing prosthesis. As shown in FIG. 16 of Givens, "client" 1600 interacts via network 1605 with a web server 1610 with an audiometer 1620. (See, Givens, FIG. 16.) "The client 1600 displays the status information **for the operator** and determines, for example, by **receiving input from the operator, if any parameters are to be changed** (block 1720)." (See, Givens, col. 23, 11. 41-44.) The changes are passed on by the web server 1610 and applied, and further changes requested from the operator "until no changes in the parameters are needed (block 1720)." (See, Givens, col. 23, 11. 51-53.) The fact that this portion of Givens focuses heavily on the clinician's interaction in changing parameters in the recipient's hearing prosthesis is further evidence that Givens describes a system which is not independent of the clinician's computer or subsystem.
>
> 15. Therefore, because Givens does not teach a system which "perform[s] the one or more tests **received from and independent of the clinician**

> **subsystem**" or "performing said customized one or more tests.., using the recipient subsystem and **independent of the clinician subsystem**, to generate the result data," Applicants assert that it is impossible for Givens to anticipate or render obvious Applicants' invention as claimed. Applicants further assert that the other art of record also fail to teach or suggest that which is missing from Givens. Therefore, Applicants respectfully request that the rejections of claims 139, 156, 165 and 174 under 35 U.S.C. § 102(e) be reconsidered, and that it be withdrawn.

The Examiner asserts that, as can be seen by the cited sections above, Givens discloses embodiments where the recipient subsystem is a "pervasive computing device that is configured to generate the desired test signals and to receive the response signals", "is configured to generate stimulation signals corresponding to the testing protocol associated with the desired test", is coupled to a probe that includes "one or more sensors 483 such as transducers and/or one or more miniaturized low noise microphones oriented and configured to sense signals evoked in the ear of the subject", and "can process the received signals into a desired format before transmitting to the remote site", all indicating that the recipient subsystem performs the testing independent of the clinician subsystem.

Givens further discloses an embodiment where the remote site (i.e. client 1600) communicates with the local site (i.e. web server 1610) and "client 1600 instructs the web server 1610 to initiate the stimulation", "server 1610 initiates the stimulation by the audiometer 1620, either directly or through the interface 1615, and collects data on the patient response" and "response data is provided to the client 1600 (block 1745) for display to the operator". Therefore, while the remote site does instruct the local site to initiate the testing, the test generation and receiving test responses are performed by the local site, independent of the remote site.

Additionally, while Applicant argues that Givens does not teach performing one or more tests by the recipient subsystem independent of the clinician subsystem because the clinician subsystem is able to change parameters, the Examiner asserts that one embodiment allowing the modification of parameters does not mean that Givens does not disclose an embodiment where parameters are not modified. In fact, the Examiner asserts that Givens is explicit in providing such an embodiment where parameters are not changed and, as such, performing the one or more tests is completely independent based on Applicant's arguments, specifically:

> FIG. 17 illustrates operations according to embodiments of the present invention. The operations illustrated in FIG. 17 may be carried out by the system of FIG. 16. As seen in FIG. 17, the client 1600 pings the web server 1610 (block 1700). If a response to the ping is not received (block 1705), operations may terminate or the ping of a same IP address or a different IP address may be performed until a response is received. If a response to the ping is received (block 1705), the client 1600 initiates a status request to the web server 1610 (block 1710). The web server 1610 collects the requested status information, for example, by requesting information from the audiometer 1620, and returns the status information to the client 1600 (block 1715). The client 1600 displays the status information for the operator and determines, for example, by receiving input from the operator, if any parameters are to be changed (block 1720).
>
> ...
>
> When no parameters are to be changed (block 1720), the client 1600 instructs the web server 1610 to initiate the stimulation (block 1735). The web server 1610 initiates the stimulation by the audiometer 1620, either directly or through the interface 1615, and collects data on the patient response (block 1740), either directly or through the interface 1615. The response data is provided to the client 1600 (block 1745) for display to the operator. If more tests are to be performed (block 1750), operations may continue from block 1720. (column 23, lines 29-44 and 54-63)

Furthermore, the Examiner again asserts that Applicant's argument is not considered to be persuasive as Applicant's claimed invention also requires control of

the recipient subsystem by the clinician subsystem during testing, for example, in claim 154 which depends from 139:

> 154. (Previously Presented) The system of claim 139, wherein said clinician subsystem is configured to control said recipient subsystem as the one or more tests is being performed.

Applicant argues:

> 17. The Examiner asserts that Faltys teaches many of the features of Applicants' claimed invention, as detailed in a prior Office Action, the Examiner acknowledges that "Faltys does not explicitly indicate that the interfaces are provided by separate computers connected by the Internet to allow independent testing to be performed by the recipient interface." The Examiner then asserts that "Alexandrescu teaches a programming hearing aid instrument and programming method thereof including a recipient interface provided by a computer located remote[ly] from a clinician interface wherein the recipient interface is operable to obtain software instructions from the hearing prosthesis, perform testing using the recipient interface and deliver data specific to the hearing prosthesis electronically to the clinician / specialist interface." (See, Office Action, pg. 19.) The Examiner justifies this combination because "it would have been obvious.., because, as suggested by Alexandrescu, the combination would have improved the recipient's programming of the device by providing specific programming for the environment in which the recipient is intending to use the device." (See, Office Action, pg. 20.)
>
> 18. Alexandrescu is directed to a programming system which comprises a "watchdog unit 41" which monitors the sound received by the hearing device in order to detect programming codes. (See, Alexandrescu, col. 4, 11. 24-29.) The programming code may be preceded by a "leader" signal and concluded by a "trailer" signal, which is used to begin and end the programming. (See, Alexandrescu, col. 4, ln. 67, col. 5, ln. 6.) A "signal processing means 5" processes sounds from the "sound pressure level sensing means 11" (e.g. microphone) and provides the signal to the recipient to provide hearing sensation, when not in programming mode. Upon detecting the "leader" signal, a switch 43 that is connected to both the signal processing means 5 and an "interface 50" directs the programming code to the "interface 50" so that the programming of signal processing means 5 can be changed. (See, Alexandrescu, col. 4, 11. 4- 35.) Interface 50 comprises "means for receiving program codes 51", a "programming interface 53" and "means for transmitting programming codes 55." (See, Alexandrescu, col. 4, 11. 4-19.) Programming

interface 53 of Alexandrescu is described as being used to "translat[e] the program codes into a programming language compatible with the programming language of the signal processing means 5, in order to program signal processing means 5." (See, Alexandrescu, col. 4, 11. 14-18.) A communication port 7 on signal processing means 5 receives the translated programming language from programming interface 53, as shown in FIG. 2 of Alexandrescu. The programming codes are described as being received and transmitted "through a telephone line." (See, Alexandrescu, col. 5, ln. 67.)

19. Alexandrescu provides a "means for transmitting programming codes 55" which is said to receive programming code from signal processing means 5, via programming interface 53 which provides any translation necessary so that the audiologist or hearing aid specialist's computer can use the codes. The means for transmitting programming codes 55 then transmits that code through output transducer 31 for transmission to the hearing aid specialist. (See, Alexandrescu, col. 5, 11. 17-22.) The means for transmitting programming codes 55 is said to also comprise a switch 61 which switches between the output 33 of the signal processing means 5 and the output 59 of the programming interface 53, to provide the signal received to the input 35 of the output transducer means [31]. Thus, when programming code is to be transmitted via programming interface 53, switch 61 switches to receive the programming codes from output 59 of interface 53. When ambient sound is to be provided via signal processing means 5 as stimulation to the user, switch 61 switches to receive the stimulation codes from output 33 of signal processing means 5. As illustrated in FIG. 7 of Alexandrescu, a hollow "acoustical adapter 101" is described as receiving "hearing instrument 1" in the funnel-shaped element 105 that is placed adjacent the telephone handset's speaker, with "telephone coupler 109" placed near the telephone handset's microphone. (See, Alexandrescu, col. 5, 11. 50-67.) Using acoustical adapter 101, Alexandrescu describes both receiving as well as transmitting programming codes for a system which receives and sends programming codes through acoustical sound.

20. Thus, Alexandrescu is described as being able to monitor ambient sound in order to either provide the ambient sound as stimulation for the patient, or to use programming code it detects in the ambient sound in order to program the signal processing means 5 in the hearing prosthesis. In addition to programming the hearing prosthesis by sending programming codes through a telephone, Alexandrescu also describes embedding programming codes into television content, for example in content with closed-captioning signals. "Thus, for example, if the particular broadcast includes a loud noise, such as an explosion, the television signal includes, shortly before the explosion, program codes to modify the response parameters of the hearing instrument for this loud noise." (See, Alexandrescu, col. 8, 11. 10-13.) Alexandrescu also describes having multiple programming units in different rooms of a patient's house, such that the patient's prosthesis can be programmed differently for each of those rooms, because "the acoustics of a user's house may be different from one room to

another." (See, Alexandrescu, col. 8, 11. 22-23.) Finally, instead of transmitting programming codes from a remote location by telephone, Alexandrescu also describes sending the programming codes through the Internet to a user's computer, where the programming codes are then "appropriately decoded.., so as to form part of the audio signal." (See, Alexandrescu, col. 8, 11. 1-3.) As described earlier, the "watchdog unit 41" is described as monitoring the audio signal in order to detect programming code and to begin and later end the programming session.

21. As set forth in §2142 of the M.P.E.P., "to establish a prima facie case of obviousness... the prior art reference (or references when combined) must teach or suggest all of the claim limitations." Without addressing the propriety of the Examiner's combination of Faltys and Alexandrescu, Applicants respectfully assert that even if the references were combined as proposed by the Examiner, the resulting combination would still fail to teach all elements of Applicants' claimed invention.

22. As noted above, Alexandrescu describes a system used to program a hearing device, and not "a system for performing one or more **tests** on a prosthesis having **one or more implantable components implanted in a recipient** comprising.., a **recipient subsystem, comprising a recipient interface, configured to receive one or more recipient input, from said recipient interface**, and to perform the one or more tests received from and **independent of the clinician subsystem** on said prosthesis, in response to said user input, to generate the **result data** for communication to said clinician subsystem." (See, Applicants' independent claim 139.) First, neither Alexandrescu nor Faltys describes, nor would the combination thereof result in, a "recipient interface configured to receive one or more recipient input from said recipient interface.., and to perform the one or more tests received from an independent of the clinician subsystem" as claimed by Applicants. Contrary to the Examiner's assertion, on page 19 of the Office Action, that Alexandrescu describes a "recipient interface provided by a computer located remote[ly] from a clinician interface wherein the recipient interface is operable to obtain software instructions from the hearing prosthesis, perform testing using the recipient interface and deliver data specific to the hearing prosthesis electronically to the clinician / specialist interface", Alexandrescu does not provide any interface which is "configured to receive one or more recipient input" as claimed by Applicants. Furthermore, Alexandrescu, nor Faltys or any device resulting from their combination, also does not describe "perform[ing] the one or more tests received from and independent of the clinician subsystem" since Alexandrescu describes all programming being initiated by and conducted with an outside source, such as "hearing aid specialist." (See, Alexandrescu, col. 5, 11. 17-47.) Furthermore, Alexandrescu describes programming the hearing device, rather than performing tests on its hearing device. When Alexandrescu states that "a hearing aid specialist may need to obtain information about the resident response parameters within the signal processing means 5", and then continues

> on to describes how the means for transmitting programming codes 55 transmits the programming codes as an audio signal through, for example, the hollow tube tool noted above, Alexandrescu is describing the hearing aid specialist receiving, analyzing and presumably providing further testing or programming codes to the hearing device user. Therefore, Alexandrescu cannot cure the admitted deficiency of Faltys, contrary to the Examiner's assertions, and therefore the combination of Faltys and Alexandrescu fails to comply with §2142 of the M.P.E.P. which requires that "to establish a prima facie case of obviousness.., the prior art reference (or references when combined) must teach or suggest all of the claim limitations." Accordingly, Applicants respectfully request that the rejections of these claims under 35 U.S.C. §103(a) be reconsidered, and that it be withdrawn.

In response to Applicant's argument that "Alexandrescu describes a system used to program a hearing device, and not 'a system for performing one or more **tests** on a prosthesis having **one or more implantable components implanted in a recipient** comprising.., a **recipient subsystem, comprising a recipient interface, configured to receive one or more recipient input, from said recipient interface**, and to perform the one or more tests received from and **independent of the clinician subsystem** on said prosthesis, in response to said user input, to generate the **result data** for communication to said clinician subsystem'" and "neither Alexandrescu nor Faltys describes, nor would the combination thereof result in, a 'recipient interface configured to receive one or more recipient input from said recipient interface.., and to perform the one or more tests received from an independent of the clinician subsystem'," the Examiner asserts that, as set forth in the Office Action, the invention of Faltys teaches a clinician subsystem, comprising a clinician interface (column 5, lines 35-50), configured to enable a clinician to provide one or more clinician input from said clinician interface to perform one or more of

selecting and customizing the one or more tests for the recipient (column 6, lines 51-55, column 7, lines 41-65, column 10, lines 26-53, and column 15, lines 34-55, and column 22, lines 51-53); and a recipient subsystem, comprising a recipient interface (column 5, lines 51-66), configured to receive one or more recipient input, from said recipient interface (column 4, lines 22-25), and to generate the result data (column 6, lines 51-55, column 14, line 53 to column 15, line 6), wherein said clinician subsystem is further configured to received said result data from said recipient subsystem (column 8, lines 10-43), and the invention of Alexandrescu is only relied upon to modify the invention of Faltys to explicitly indicate that the interfaces are provided by separate remote computers connected by the Internet to allow independent testing to be performed by the recipient interface.

The Examiner also maintains that Alexandrescu teaches a programmable hearing aid instrument and programming method thereof including a recipient interface (column 4, lines 4-19) provided by a computer located remote from a clinician interface (column 8, lines 19-33) wherein the recipient interface is operable to obtain software instructions from the hearing prosthesis (column 5, lines 37-49), perform independent testing using the recipient interface (column 8, lines 19-33) and deliver data specific to the hearing prosthesis (i.e. results) electronically to the clinician/specialist interface (column 5, lines 17-20) using the Internet (column 7, line 66 to column 8, line 4). The Examiner further maintains that Alexandrescu does teach performing independent testing using the recipient interface because, while

Alexandrescu does teaching means for programming, Alexandrescu further teaches testing the hearing device to obtain resident response parameters.

Second, in response to Applicant's argument that "Contrary to the Examiner's assertion, on page 19 of the Office Action, that Alexandrescu describes a 'recipient interface provided by a computer located remote[ly] from a clinician interface wherein the recipient interface is operable to obtain software instructions from the hearing prosthesis, perform testing using the recipient interface and deliver data specific to the hearing prosthesis electronically to the clinician / specialist interface', Alexandrescu does not provide any interface which is "configured to receive one or more recipient input" as claimed by Applicants", the Examiner again asserts that the invention of Faltys already teaches a clinician interface (column 5, lines 35-50), configured to enable a clinician to provide one or more clinician input from said clinician interface to perform one or more of selecting and customizing the one or more tests for the recipient (column 6, lines 51-55, column 7, lines 41-65, column 10, lines 26-53, and column 15, lines 34-55, and column 22, lines 51-53), and the invention of Alexandrescu is only relied upon to modify the invention of Faltys to explicitly indicate that the interfaces are provided by separate remote computers connected by the Internet to allow independent testing to be performed by the recipient interface.

Third, in response to Applicant's argument that "Alexandrescu, nor Faltys or any device resulting from their combination, also does not describe 'perform[ing] the one or more tests received from and independent of the clinician subsystem' since Alexandrescu describes all programming being initiated by and conducted with an outside source, such as 'hearing aid specialist.'", the Examiner asserts that Alexandrescu explicitly indicates that the clinician may need to obtain resident response parameters:

> However, in some circumstances, a hearing aid specialist may need to obtain information about the resident response parameters within the signal processing means 5 before programming the signal processing means 5. To that effect, the hearing instrument 1 also includes means for transmitting program codes 55. (column 5, lines 17-21)

The Examiner further asserts that such resident response parameters are obtained independent from the clinician using the recipient interface:

> Another advantage of the present invention is that program codes may be permanently encoded into a programming unit. For example, the acoustics of a user's house may be different from one room to another. Preferably, the programming units should be located at strategic locations around the user's house, each programmed with the appropriate program codes for each of these locations. The programming unit would intermittently or continuously send into the vicinity of the programming unit the program codes, either as part of an audio signal, or preferably as part of an electromagnetic signal. Thus, whenever the user and, by the same token, the hearing instrument would be located near the programming unit, the hearing instrument would be automatically programmed with the appropriate program codes for a given location. (column 8, lines 19-33)

Finally, in response to Applicant's argument that "Alexandrescu describes programming the hearing device, rather than performing tests on its hearing device", the Examiner maintains that, as noted above, Alexandrescu does teach performing

independent testing using the recipient interface because, while Alexandrescu does teaching means for programming, Alexandrescu further teaches testing the hearing device to obtain resident response parameters.

***Conclusion***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

U.S. Patent No. 6,334,072 to Leysieffer teaches a system for performing a test on a hearing prosthesis implanted in a recipient (column 8, lines 24-26) comprising: a testing computer (column 6, lines 49-52) comprising a processor configured to process software instructions and to output signals in response to said processed software instructions (column 7, lines 38-52); a prosthesis interface configured to transfer said outputted signals from said testing computer to the hearing prosthesis interfaced with said testing computer (column 6, lines 45-64); and a recipient interface configured to receive a control input from the recipient of the hearing and to cause said processor to perform said test in response to said control input (column 6, line 65 to column 7, line 7).

U.S. Patent No. 6,115,478 to Schneider teaches an apparatus for and method of programming a digital hearing prosthesis comprising a local system and computer and a remote system and computer wherein the remote system controls the local system to initiate synthesizing signals for transmission to the hearing prosthesis (column 9, lines 50-58).

U.S. Patent No. 6,879,693 to Miller et al. teaches a method and system for external assessment of hearing aids that include implanted actuators.

U.S. Patent Application Publication No. 2002/0176584 to Kates teaches an apparatus and methods for hearing aid performance measurement, fitting, and initialization.

U.S. Patent No. 6,366,863 to Bye et al. teaches a portable hearing-related analysis system.

U.S. Patent No. 6,115,478 to Schneider teaches an apparatus and method of programming a digital hearing aid.

U.S. Patent No. 4,847,617 to Silvian teaches a high speed digital telemetry system for implantable devices.

U.S. Patent No. 5,609,616 to Schulman et al. teaches a physician's testing system and method for testing an implantable cochlear stimulator.

U.S. Patent No. 7,181,297 to Pluvinage et al. teaches a system and method for delivering customized audio data.

EP Patent Application Publication No. 0 124 930 to Crosby et al. teaches a cochlear implant system for an auditory prosthesis.

10. This Action is based on a Request for Continued Examination. All claims are drawn to the same invention claimed earlier and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered earlier. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action

in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY R. WEST whose telephone number is (571)272-2226. The examiner can normally be reached on Monday through Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eliseo Ramos-Feliciano can be reached on (571)272-7925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey R. West/
Primary Examiner, Art Unit 2857

June 11, 2009